PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Form PCT/IPEA/416
VO/3-33379A		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP2004/010696	23.09.2004	24.09.2003

International Patent Classification (IPC) or national classification and IPC
A61K9/28

Applicant
NOVARTIS CONSUMER HEALTH S.A.

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☐ *sent to the applicant and to the International Bureau)* a total of sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
15.06.2005	22.11.2005

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/EP2004/010696

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

   Description, Pages

   1-4 as originally filed

   Claims, Numbers

   1-8 as originally filed

   ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-8
	No:	Claims	
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-8
Industrial applicability (IA)	Yes:	Claims	1-8
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Re Item V.
Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

The following documents are referred to in this communication:

D1 : WO 99/51209 A (IMPAX) 14 October 1999 (1999-10-14)
D2 : EP 0 347 748 A (ABBOTT) 27 December 1989 (1989-12-27)
D3 : FR 2 404 029 A (SANKYO) 20 April 1979 (1979-04-20)

Unless otherwise indicated, reference is made to the relevant passages emphasized in the International Search Report.

V.1. The present application does meet the criteria of **Article 33(1) PCT**, because the subject-matter of **present claims 1-8** is new in the sense of **Article 33(2) PCT**.
In fact, the entire unique combination of excipients for the manufacture of coating films for diclofenac (salt) core tablets claimed in present **independent claims 1** is not disclosed or claimed in any of the prior art documents.

V.2. The present application does not meet the criteria of Article 33(1) PCT, because the subject matter of **present claims 1-8** does not involve an inventive step in the sense of **Article 33(3) PCT.**
In fact, the **document D1**, which is considered to represent the most relevant state of the art to the subject matter of **present independent claim 1**, discloses (the references in parentheses applying to this document) active , immediate release core tablets (containing e.g. **diclofenac sodium** and a major amount of **microcrystalline cellulose**) that are press-coated by a (inert or active: ***see D1, page 5, lines 9-11***) layer of a mix of a **hydrophilic polymer** (e.g. **hydroxypropyl methylcellulose HPMC or microcrystalline cellulose MC**) and a **hydrophobic polymer or substance** or compound (e.g. a wax , oil, glyceride or **STEARIC ACID**). It should be here emphasized that **IN THE EXAMPLES A MIX OF COMPARABLE AMOUNTS OF HPMC AND MC IS USED**, although the preferred hydrophobic compound seems to be hydrogenated vegetable oil type I ***(see in particular D1, Tables).***
Therefore the subject-matter of **present independent claim 1** differs from the disclosure of D1 only in that the coating composition for diclofenac (salt) core tablets should contain **hydroxypropyl methylcellulose and microcrystalline cellulose** in association uniquely

with **stearic acid** as hydrophobic compound of choice.

The problem to be solved by the present invention may in fact be regarded as to provide for the preparation of coating compositions for diclofenac (salt) core tablets endowed with favourable and beneficial properties.

However, in view of **D3** the solution proposed in independent claim 1 of the present Application (i.e. the selective choice of stearic acid) cannot be considered as involving an inventive step (**Article 33(3) PCT**) because **D3** clearly discloses that the **specific addition of stearic acid** (and optionally other components, such as **titanium dioxide**) **to HPMC dispersions** does provide for injestible coating compositions endowed with favourable and beneficial properties when applied to core tablets containing non-steroidal anti-inflammatory compounds (like substituted indanylpropionic acids: ***see in particular D3, Examples).***

Therefore the features disclosed in D1 and D3 would be combined by the skilled person, without exercise of any inventive skills in order to solve the problem posed. The proposed solution in independent claim 1 thus cannot be considered inventive (**Article 33(3) PCT**).